

company announcement

Novo Nordisk receives positive opinion from the European regulatory authorities for Refixia® (nonacog beta pegol, N9-GP) for the treatment of haemophilia B

Bagsværd, Denmark, 24 March 2017 – Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP), under the European Medicines Agency (EMA), adopted a positive opinion for the use of Refixia® (nonacog beta pegol, N9-GP), recommending marketing authorisation for the treatment of adolescents and adults with haemophilia B.

The CHMP recommends Refixia®, the brand name for nonacog beta pegol, N9-GP, to be indicated for prophylaxis and on-demand treatment of bleeding as well as for surgical procedures in adolescent (≥ 12 years of age) and adult patients with haemophilia B (congenital factor IX deficiency). The recommendation is based on the results from the paradigm clinical trial programme, where 115 previously treated children and adults with haemophilia B were treated with Refixia®.

“We are excited about the positive opinion obtained for Refixia® and it represents a significant milestone in our efforts to expand the treatment options for patients with haemophilia,” said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer of Novo Nordisk. “We believe Refixia® with its strong clinical profile provides haemophilia B patients better protection against bleeds, even into damaged joints, and an overall improved quality of life.”

About Refixia®

Refixia® (nonacog beta pegol, N9-GP) is an extended half-life factor IX molecule for replacement therapy in patients with haemophilia B. Glycopegylation, the prolongation technology used for the half-life extension, is a novel approach in haemophilia B. Pegylated products have been approved in haemophilia A and other therapeutic areas. The review of Refixia® was based on the paradigm programme, a phase 3 clinical programme enrolling children and adults with severe or moderately severe haemophilia B. In the programme, 115 previously treated patients had a total of more than 8,800 exposure days for up to 2.7 years of treatment with Refixia®.

About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,000 people in 77 countries and markets its products in more than 165 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

Further information

Media:

Katrine Sperling	+45 3079 6718	krsp@novonordisk.com
Ken Inchausti (US)	+1 609 786 8316	kiau@novonordisk.com

Investors:

Peter Hugrefte Ankersen	+45 3075 9085	phak@novonordisk.com
Hanna Ögren	+45 3079 8519	haoe@novonordisk.com
Anders Mikkelsen	+45 3079 4461	armk@novonordisk.com
Kasper Veje (US)	+1 609 235 8567	kpvj@novonordisk.com